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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,423	09/27/2001	Amos Nussinovitch	919 1002	7772
21831	7590	04/07/2004	EXAMINER	
STEINBERG & RASKIN, P.C. 1140 AVENUE OF THE AMERICAS, 15th FLOOR NEW YORK, NY 10036-5803			NAFF, DAVID M	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/856,423	NUSSINOVITCH ET AL.	
	Examiner	Art Unit	
	David M. Naff	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 26 January 2004.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-10,13,14 and 21-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-10,13,14 and 21-46 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some *
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for 5 continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/26/04 has been entered.

The amendment of 1/26/04 amended the title, amended claim 1, 10 canceled claims 11, 12 and 15-20, and added new claims 21-46.

Claims examined on the merits are 1-10, 13, 14 and 21-46 which are all claims in the application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

15 **Specification**

The disclosure is objected to because of the following informalities: in the title "(MINIMAL VOLUME)" is uncertain as to meaning and scope and should be deleted. Being minimal is relative and subjective and of indeterminate scope.

20 Appropriate correction is required.

Claim Objections

Claims 1-10, 13, 14 and 21-46 are objected to because of the following informalities: the claims are confusing by not being in consecutive order. For example claims 13, 14, canceling of claims 15-25 20 and new claims 21-25 are presented before reciting claims 4-10 and

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canceling claims 11 and 12, and new claims 26-46 are separated from new claims 21-25 by being recited after claims 4-10 and canceling of claims 11 and 12.

Appropriate correction is required.

5

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

10 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15

Claims 1-10, 13, 14 and 21-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject, matter which was not described in the specification in such a way as to reasonably convey 20 to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Support is not found in the specification for using a capillary means by sucking a cell or embryo into a capillary as required by claims 1. While the specification discloses (page 4, line 2) sucking 25 an embryos into a 1.5 mm diameter tube, this does not support sucking into any capillary. It is has not been established that the tube is a capillary, and if a capillary, the use of only this tube is supported. Additionally, the disclosed use of the tube is only when sucking an

embryo into the tube, and does not support sucking a cell into the tube.

Support is not found in the specification for the ranges of "1 to 5%" and "6 to 8%" recited in claims 1 and 28. The page and lines 5 where these ranges are recited should be pointed out.

Support is not found in the specification for the coating being transparent as in claims 23 and 42 and the coating accumulating photons as in claims 24 and 43. The page and lines should be pointed out where the coating being transparent and accumulating photons is 10 recited recited.

Support is not found in the specification for a capillary as required by claims 21 and 40. The page lines should be pointed out where the condition of these claims is recited.

Claim Rejections - 35 USC § 112

15 The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

20 Claims 1-10, 13, 14 and 21-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

25 The claims are confusing by claims 1 and 28 reciting "producing a very thin uniform cross-linked hydrocolloid coating of a single cell produced by capillary means". The meaning and scope of "very thin"

is uncertain. Being very thin is relative and subjective, and it is unclear as to whether the cell or coating is produced by capillary action. It is suggested the title be changed to way it was before the amendment.

5 In line 9 of claim 1, ", in cases" should be changed to --- when the hydrocolloid is --- and change "and" before "kappa" to --- or ---. This type of change should be made to line 10, and the changes should also be made to claim 28. In line 10 of claim 1, the full name should be used instead of the abbreviation, "LMP", to be clear.

10 Claims 21 and 40 are unclear as to the meaning of "cell or embryo to be coated is maneuvered". When does this occur in claims 1 and 28. additionally, the meaning and scope of "minimal thickness". Being minimal is relative and subjective.

15 Claims 22 and 41 are unclear how they further limit claims 1 and 28 by requiring a uniform coating on all sides of the coated cell or embryo since claims 1 and 28 require an uniform coating and such a coating is inherently uniform on all sides or the coating is not uniform.

20 Claims 7 and 34 are unclear by requiring both egg and embryos. Claims 1 and 28 do not require both an egg and an embryo since claim 1 is limited to a cell and claim 28 to an embryo. Additionally, an embryo is not an embryo, and it does not appear both would be coated together by reciting "and".

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Claims 1-5, 8-10, 13, 14 and 21-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nussinovitch et al (6,068,867) in view of Soon-Shiong et al (5,762,959) and Dorian et al (5,693,514) and Togawa (5,348,883) (newly applied).

5 The claims are drawn to coating a cell or embryo by placing the cell or embryo in a hydrocolloid solution, removing the cell or embryo from the solution by sucking into a capillary, placing the cell in a cross-linking solution to provide the cell with a thin coat of the hydrocolloid, and storing the cell in solution.

10 Nussinovitch et al disclose coating various materials such as bulbs, fungi, etc. (Col 3, lines 1-4) by placing material in a hydrocolloid solution such as an alginate solution, allowing excess solution to drip from the material and immersing the material in a gel inducing agent such as chloride salt or calcium salt. For example, 15 see col 1, line 42 to col 3, line 20, and Examples 1 and 2.

Soon-Shiong et al disclose microencapsulation of cells in alginate.

Dorian et al disclose using non-fibrogenic high mannuronate alginate to coat transplants such as pancreatic islets.

20 Togawa discloses removing liquid by sucking the liquid through a capillary (col 7, line 9) when carrying out a method of selecting cells.

It would have been obvious to apply the alginate coating procedure of Nussinovitch et al to a cell in view of Soon-Shiong et al 25 microencapsulating cells in alginate and Dorian et al coating islets with high mannuronate alginate, and since Nussinovitch et al disclose using the coating procedure to coat different materials including

fungi. Using capillary to remove the cell from the hydrocolloid solution by sucking the cell into the capillary would be obvious in view of Togawa removing a solution by sucking it through a capillary. Storing the cell in solution would have been obvious since Soon-Shiong et al and Dorian et al may store cells in solution. No unexpected result has been established by storing in solution as compared to drying.

Response to Arguments

Applicants urge that coating a single cell by sucking a cell into a capillary is not suggested by Nussinovitch et al, Soon-Shiong et al and Dorian et al. However, Togawa would have suggested using a capillary to remove cells and an embryo from the hydrocolloid solution, and this would have resulted in coating single cells. Moreover, the specification shows only sucking an embryo into a 1.5 mm tube, and contains no disclosure of sucking a single cell into a capillary. An embryo contains multiple cells and is not a single cell. It has not been established by evidence that sucking the embryo into the tube provides a thinner coating than obtained by Nussinovitch et al. The percent thickness of the coating in claims 1 and 28 would have been inherent in the coating of Nussinovitch et al.

Claim Rejections - 35 USC § 103

Claim 7 and 28-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1-5, 8-10, 13, 14 and 21-27 above,
and further in view of Jorgensen et al (5,293,838).

The claims require coating an embryo or the cell to be an Xenopus laevis egg or embryos.

Jorgensen et al disclose protecting an egg by encapsulating the egg in a gel material (col 1, lines 54-60).

5

When applying the coating procedure of Nussinovitch et al to a cell as set forth above, it would have been obvious to apply the coating to a Xenopus laevis egg or embryos to obtain the protective function of the coating as suggested by Jorgensen et al.

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Response to Arguments

The comments above in response to arguments also apply to this rejection.

Conclusion

Any inquiry concerning this communication or earlier 15 communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-20 0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for 5 unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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David M. Naff
Primary Examiner
Art Unit 1651

DMN
4/5/04